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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,878	05/31/2006	Hisami Shinohara	1083-4	6677

25903 7590 08/09/2007

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EXAMINER	
VAKILI, ZOHREH	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,878	SHINOHARA ET AL.	
	Examiner	Art Unit	
	Zohreh Vakili	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7,8,11,13,15 and 22-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7,8,11,13,15 and 22-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/21/2004 & 01/23/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-4, 7-8, 11, 13, 15, 22, 23-33 are presented for examination

LACK OF WRITTEN DESCRIPTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

Claims 7, 26, and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 7, 26, and 31 are directed to encompass derivatives, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these derivatives, meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath, Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

With the exception of the above specifically disclosed chemical structures, the skiled artisan cannot envision the detailed chemical structure of the encompassed derivatives, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.,* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli,* 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive

means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-8, 11, 13, 15, 22, 23-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Paul (US Patent No. 6149924).

Paul teaches compositions containing branched-chain amino acids and their derivatives and optionally medium chain fatty acids and a mixture of vitamins and minerals for enhancing lipid production and improving the barrier functions in the mammalian skin (see col. 1, lines 7-13). During youth, the blood circulation delivers to

the skin all the necessary ingredients for lipid synthesis. However, as we age, the blood flow to the skin decreases. This results in decreased delivery of the lipid building nutrients to the skin (col. 1, lines 41-44). Similarly, skin care compositions are also known to include caprylic acid (also known as octanoate or octanoic acid), either as free acid, but more often in an esterified form as caprylic/capric acid triglycerides. (see col. 2, lines 38-53). Accordingly, it is an object of embodiments of the present invention to provide a skin treatment composition for increasing lipid production in mammalian skin (see col. 2, lines 59-61). Individuals whose rate of skin lipid synthesis declines faster than others; examples include, but are not limited to diabetics, smokers, chronic consumers of alcohol, and post-menopausal women (see col. 19, lines 43-46). Because the composition will improve the barrier function of the skin, therefore, it is beneficial to individuals living in cold climates and exposed to cold temperatures (col. 21, lines 37-38). In one preferred embodiment, a composition of the present invention comprises a mixture of L-leucine, L-isoleucine, L-valine, medium chain fatty acids (**octanoate** and/or **hexanoate**) in an admixture with vitamins. The vitamin composition includes, but not limited to, **vitamin B5** (Panthenol), **vitamin B6** (Pyridoxine), vitamin H (Biotin), and **vitamin E** (see col. 21, lines 39-45). The composition may further contain other vitamins, such as vitamin A, vitamin C, vitamin B (thiamin), vitamin B3 (niacin), lipoic acid, and mixtures thereof. The composition may contain minerals and trace elements, such as **magnesium** and/or manganese or their salts (see col. 21, lines 49-55). See table A for an acceptable formulation which comprises **medium chain fatty acid** and **vitamins** (see col. 22, lines 10-20).

An important ingredient of the composition are enzyme activators. Advantageous activators are selected from the group consisting of octanoic acid, hexanoic acid, alpha keto isocaproic acid, alpha chloroisocaproic acid, thiamin diphosphate and their derivatives and mixtures thereof. The derivatives can include esters with alcohol or cholesterol, and mono-, di- and **triglycerides** of octanoic acid or hexanoic acid (see col. 9, lines 24-40). Another preferred optional ingredient includes essential fatty acids (EFAs), i.e., those fatty acids which are essential for the plasma membrane formation of all cells. EFAs also enhance lipid production of epidermis and provide lipids for the barrier formation of the epidermis. These essential fatty acids are preferably chosen from **linoleic acid**, gamma-linoleic acid, homo-gamma-linoleic acid, columbinic acid, arachidonic acid, **gamma-linolenic acid**, timnodonic acid, hexaenoic acid and mixtures thereof (see col. 17. lines 20-25).

Consequently, the reference anticipates the claimed invention defined in claims 1-4, 7-8, 11, 13, 15, 22, 23-33.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13, 15, 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Seiden (US Patent No. 5071669).

Seiden teaches a reduced calorie fat compositions which contain combinations of substantially nonabsorbable, substantially nondigestible polyol polyesters and certain reduced calorie triglycerides that function as anti-anal leakage agents and provide textural/taste benefits are disclosed. These reduced calorie fat compositions are useful in a variety of food applications, including frying oils for salted snacks, chocolate-flavored candy bars and cooking/salad oils (see abstract). By "medium chain saturated fatty acids," as used herein, is meant C6:0 (caproic), CB:8:0 (caprylic), or C10:0 (capric) fatty acids, or mixtures thereof. The C7 and C9 saturated fatty acids are not commonly found, but they are not excluded from the possible medium chain fatty acids. The present medium chain fatty acids do not include lauric acid (C12:0), sometimes referred to in the art as a medium chain fatty acid (see col. 3, lines 29-36). The polyol starting material having at least 4 hydroxy groups must have at least 4 of these groups esterified with a fatty acid containing from 2 to 24 carbon atoms, preferably from 8 to 22 carbon atoms, and most preferably from 12 to 18 carbon atoms. Examples of such fatty acids include acetic, butyric, caproic, caprylic, capric, lauric, myristic, myristoleic, palmitic, palmitoleic, stearic, oleic, elaidic, ricinoleic, linoleic, linolenic, eleostearic, arachidonic, behenic, and erucic acid. The fatty acids can be derived from naturally occurring or synthetic fatty acids. Suitable sources of naturally occurring fatty acids include soybean oil fatty acids, canola oil fatty acids (i.e. fatty acids derived from low euricic acid rapeseed oil), sunflower seed oil fatty acids,

sesame seed oil fatty acids, safflower oil fatty acids, palm kernel oil fatty acids, and coconut oil fatty acids (see col. 4, lines 53-68 & col. 5, lines 1-2). Medium chain saturated fatty acids can be obtained from coconut, palm kernel, or babassu oils. They can also be obtained from commercial medium chain triglycerides (see col. 9, lines 34-37). The present reduced calorie fat compositions can also be fortified with vitamins and minerals, particularly the fat-soluble vitamins. Vitamin E (tocopherol) vitamin can be used in the present invention (see col. 15, lines 54-68). Vitamins that are insoluble in fat can similarly be included in the present reduced calorie fat compositions. Among these vitamins are the vitamin B complex vitamins, vitamin C, vitamin G, vitamin H, and vitamin P. The minerals include the wide variety of minerals known to be useful in the diet, such as calcium, magnesium, and zinc. Any combination of vitamins and minerals can be used in the present reduced calorie fat compositions. The present reduced calorie fat compositions are particularly useful in combination with particular classes of food and beverage ingredients (see col. 16, lines 21-32). The reduced calorie fat compositions can be used in combination with other noncaloric or reduced calorie fats, such as branched chain fatty acid triglycerides. Other partial fat replacements useful in combination with the fat materials are medium chain triglycerides (see col. 16, lines 52-60).

Consequently, the reference anticipates the claimed invention defined in claims 13, 15, 30-33.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner 1614

August 1, 2007

Ardin H Marschel 8/5/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER